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TITLE: Ovarian Cancer Risk and Survival in BRCA 1/2 Carriers

PRINCIPAL INVESTIGATOR: Francesmary Modugno, Ph.D., M.P.H.

CONTRACTING ORGANIZATION: University of Pittsburgh
Pittsburgh, Pennsylvania 15260

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Francesmary Modugno, Ph.D., M.P.H.

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
University of Pittsburgh
Pittsburgh, Pennsylvania 15260

E-Mail: fm@cs.cmu.edu

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13. Abstract ***(Maximum 200 Words)*** *(abstract should contain no proprietary or confidential information)*
This project is evaluating whether oral contraceptives and parity are as protective against ovarian cancer in BRCA1/2 carriers as they are for women in general. It is also determining whether there are survival differences between BRCA1/2 carriers with ovarian cancer compared to women with sporadic disease. The study employs a case-case design. We will identify about 400 Jewish women with epithelial ovarian cancer. We will genotype these women for the 3 BRCA1/2 mutations found in Ashkenazi women. We will then compare oral contraceptive use and parity between carriers and non-carriers. We will also compare survival differences between the two groups. In the first year of the project, we have identified 36 eligible subjects. Risk factor data and pathologic specimens have been obtained on these women. Using the pathology specimens, we have genotyped the 36 subjects and identified 17 mutation carriers. To date, we are on schedule to complete this project as outlined in the original Work Plan.

14. Subject Terms (keywords previously assigned to proposal abstract or terms which apply to this award)
prevention, chemoprevention, epidemiology, molecular epidemiology, etiology, *BRCA1/2*, risk factors, oral contraceptives, parity, survival

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Table of Contents

INTRODUCTION:

The goal of this project is to determine whether oral contraceptives (OCs) and parity are as protective against ovarian cancer in BRCA1/2 carriers as they are for women in general. The second goal is to determine whether there are survival differences between BRCA1/2 carriers with ovarian cancer compared to women with sporadic disease. The study employs a case-case design. We will identify about 400 Jewish women with epithelial ovarian cancer. We will genotype these women for the 3 BRCA1/2 mutations found in Ashkenazi women. We will then compare oral contraceptive use and parity between carriers and non-carriers. We will also compare survival differences between the two groups.

BODY:

In this section, we describe our accomplishments according to the Work Plan originally approved. Accomplishments are shown in *italics.*

Task 1 Preparation for Study, Months 1-6:

a. Any remaining IRB approvals will be obtained
   - *All IRB approvals have been obtained. Specifically, we have obtained approval from North Shore University Hospital, which houses approximately 50% of the study samples (see attached letter in the Appendix).*

b. The Medical Record Abstraction form will be tested on a subset of subjects and revised accordingly
   - *We tested the form and in conjunction with Dr. Edwards, the project gynecologic oncologist, we have updated it*

c. A study database will be designed and relevant data from previous studies will be downloaded
   - *We have designed the study database*
   - *Relevant data from the SHARE study was downloaded on the 36 subjects identified as Jewish in the parent study and for whom pathologic specimens were obtained*

d. A study key will be created
   - *A study key was created and is maintained by Dr. Nelson at the University of Pennsylvania*

Task 2 Performance of Laboratory Assays, Months 1-28:

a. Specimens (400) will be located, cut, labeled with the new study ID and shipped to the core lab
   - *36 specimens were located, cut, labeled with the new Study ID and shipped to Dr. Kant's Laboratory (the project genotyping laboratory).*

b. Assays (400) to detect *BRCA1/2* mutations will be performed and the results recorded on study forms
   - *The 36 specimens were genotyped for the 3 Ashkenazi mutations. Among the 36 subjects, we found 17 mutations carriers.*

c. A subset of specimens (80) will be retested to validate the laboratory results
   - *10 specimens were retested to confirm genotyping results. All retests agreed with the original assay results, providing assay validity.*

Task 3 Preparation for Medical Record Abstraction and Data Entry, Months 6-12:

a. The Medical Record Abstraction form will be finalized and the investigator trained to perform patient data reviews using the instrument
   - *The form was finalized and we are training the North Shore University Hospital Investigator, the site with the largest number of subjects, to perform the abstraction*

b. The computerized data entry form for medical record data will be designed and implemented in PoP
   - *The form was implemented using TELEform, an automated data entry system. We chose TELEform instead of the PoP system as originally proposed because TELEform supports automated data entry and should greatly diminish the time for and increase the accuracy of data entry required by this project.*

c. The computerized data entry form for laboratory assay data will be designed and implemented in PoP
   - *Because this form is so simple, Dr. Kant's Laboratory employs a Microsoft Excel form for data entry. We have decided that this is sufficient and compatible with our data entry system.*

In addition, although not listed in the Work Plan, we hired a part time project manager (Pam Overberger, MS) to oversee the work, including obtaining specimens, maintaining IRBs, implementing the data entry forms in TELEform, implementing the study database and generating preliminary reports.

KEY RESEARCH ACCOMPLISHMENTS:

Because this is the first year of the project, our data analyses are preliminary and limited to the 36 subjects that we genotyped for the 3 Ashkenazi mutations. Our results are as follows:

Mean age at diagnosis:	54.6 years
Family History of Ovarian Cancer:	6
Nulliparous	8
No. Live births (among parous women)	1.9

OC use	16
OC duration (among users)	3.5 years
Mutation Carriers	17

Because of the small numbers, we did not do any further analyses, nor did we compare carriers to non-carriers. Such results at this point would be meaningless. Nonetheless, these data provide evidence of our accomplishments to date: identifying eligible participants and pertinent data, obtaining specimens, and genotyping specimens.

REPORTABLE OUTCOMES:
No reportable outcomes have been obtained thus far. We anticipate a preliminary manuscript describing the OC and parity endpoints next year.

CONCLUSIONS:
In conclusion, this project is on target to complete the work as outlined in the Work Plan. We anticipate providing data on the role of OCs and childbearing on the risk of ovarian cancer associated with BRCA1/2 carriage. Such data will be directly useful by clinicians counseling women about ways to reduce their risk of ovarian cancer, as well as by researchers seeking prevention/intervention strategies for high-risk women.

We further anticipate providing data on treatment outcome for carriers compared to non-carriers. These data will have implications for the treatment of the disease and may suggest areas for further research in ovarian cancer treatment.

REFERENCES: NONE

APPENDICES:
IRB Approval letter from North Shore University Hospital
Medical Record Abstraction Form implemented in TELEform.

NORTH SHORE - LONG ISLAND JEWISH HEALTH SYSTEM

North Shore University Hospital
Institutional Review Board
5 Dakota Drive, Suite 306 * Lake Success, New York 11042
Telephone: (516)719-3100 * Facsimile: (516)719-3110

27 April 2001

Dear A. Menzin, MD:

Your proposal entitled ***#00-155: Ovarian Cancer Risk and Survival*** was reviewed by the Institutional Review Board on August 17, 2000. The **revised Form 4, clarification that only North Shore University Hospital at Manhasset will participate, clarification that only the following investigators will participate in the project: Drs. Menzin, Modugno, Ness, Belle, Edwards, Kant, Naus, and Ms. Gaetano; and receipt of evidence of completion of humans subjects protections programs for all investigators** you have submitted in response to their comments has/have been reviewed.

You now have **administrative approval** to begin the project. This approval will be brought to the IRB for their information and acknowledgment at their meeting on May 17, 2001. A progress report for the project is due in August 2001.

Sincerely yours,

Jacki Altman
Director

Administrative Approval
Revised 2/01

Draft

OVARIAN CANCER RISK AND SURVIVAL STUDY

A. DATA FORM INFORMATION

A1. Study ID Number: [ ][ ][ ][ ][ ][ ]

A2. Date Completed: [ ][ ] / [ ][ ] / [ ][ ][ ][ ]
mo da yr

A3. Completed By: _____

B. GENERAL PATIENT INFORMATION

B1. Birth Date: [ ][ ] / [ ][ ] / [ ][ ][ ][ ]
mo da yr

B2. Height: [ ] [ ][ ] (Use 9's if unknown)
ft. in.

B3. Weight: [ ][ ][ ] (Use 9's if unknown)
lbs.

B4. At dx, subject was:
- O premenopausal
- O perimenopausal
- O postmenopausal.....;if post, age at menopause: [ ][ ] yrs.
- O unknown

B5. Age at menarche: [ ][ ] (Use 9's if unknown)
yrs.

B6. History of Cancer in Mother, Father, Sister or Brother:

Ovarian:
O No O Yes O Unknown

Breast:
O No O Yes O Unknown

Colon:
O No O Yes O Unknown

Lung:
O No O Yes O Unknown

Prostate:
O No O Yes O Unknown

Other Cancer:
O No O Yes O Unknown

If Other, please specify type:
[ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ]

OVARIAN CANCER RISK AND SURVIVAL STUDY

B7. Number of Pregnancies: [ ][ ] (Use 00 if never pregnant; use 99 if unknown)

If one or more pregnancies:

B7.1. Number of Term Deliveries (greater than 28 weeks): [ ][ ]
(Use 99 if unknown)

B7.2. Number of Therapeutic Abortions (28 weeks or fewer): [ ][ ]
(Use 99 if unknown)

B7.3. Number of Spontaneous Abortions (28 weeks or fewer): [ ][ ]
(Use 99 if unknown)

B8. Oral Contraceptive Use: ○ No
○ Yes ---- B8.1. Number of Months Used Over the Lifetime: [ ][ ][ ]
(Enter 999 if unknown)
○ Unknown

B9. Non-Contraceptive Estrogen Use Only (with or without Progestin): ○ No
○ Yes
○ Unknown

B9.1. Number of Months Used Over the Lifetime: [ ][ ][ ]
(Enter 999 if unknown)

B10. Personal History of Other Cancer:

			Month & Year of Diagnosis:	
Breast :				
O No	O Yes	O Unknown	/	*(Use 02/2020 if unknown)*
Colon:				
O No	O Yes	O Unknown	/	
Endometrium:				
O No	O Yes	O Unknown	/	
Lung:				
O No	O Yes	O Unknown	/	
Other Cancer:				
O No	O Yes	O Unknown	/	

If Other, please specify type:

B11. Previous Hysterectomy: O None

O Abdominal

O Vaginal

O Hysterectomy, NOS

If Hysterectomy performed, date: / / (mo / da / yr)

(Use 02/02/2020 if unknown)

(Do not include hysterectomies done as part of the surgery for ovarian cancer treatment.)

B12. Tubal Ligation: O No

O Yes

O Unknown

If Tubal Ligation performed, date: / / (mo / da / yr)

(Use 02/02/2020 if unknown)

OVARIAN CANCER RISK AND SURVIVAL STUDY

C. INITIAL DIAGNOSIS

C1. Date of Initial Diagnosis: ☐☐ / ☐☐ / ☐☐☐☐ (Use 02/02/2020 if unknown)
mo da yr

C2. Ascites: ○ Not Present ○ Present ○ Unknown

IF ASCITES PRESENT:

C2.1. Cytology Results: ○ Negative for cancer
○ Positive for cancer
○ Atypical, highly suspicious for cancer
○ Cytology not done
○ Cytology done, results unknown

C2.2. Amount of Ascites: ○ Volume not measured
○ Volume measured, amount unknown
○ Volume measured

If measured: C2.3. Actual Volume (in liters): ☐☐

Use 1 for less than 1 liter
Use 7 for 7 or more liters
Use 99 if unknown

C3. Tumor Markers (Preoperative):

C3.1. Alphafetoprotein (AFP)
○ Negative
○ Positive
○ Not Done
○ Unknown
If positive, AFP Level ☐☐☐☐☐

C3.2. Beta HCG (Human chorionic gonadotropin)
○ Negative
○ Positive
○ Not Done
○ Unknown
If positive, HCG Level ☐☐☐☐☐

C3.3. CA-125
○ Negative
○ Positive
○ Not Done
○ Unknown
If positive, CA-125 Level ☐☐☐☐☐

C3.4. Carcinoembryonic antigen (CEA)
- O Negative
- O Positive
- O Not Done
- O Unknown

If positive, CEA Level

C3.5. Hemoglobin
- O Negative
- O Positive
- O Not Done
- O Unknown

If positive, Hemoglobin Level

C3.6. Other
- O Negative
- O Positive
- O Not Done
- O Unknown

Level if positive:

If Other, please specify:

C4. Surgical Evaluation Performed:

Dilatation and curettage
O No O Yes O Unknown

Laparoscopy
O No O Yes O Unknown

Date of Procedure

mo / da / yr

(Use 02/02/2020 if unknown)

C5. Laterality of Primary Site:
- O right ovary
- O left ovary
- O only one side involved, left or right unspecified
- O bilateral involvement
- O laterality unknown

C6. Histology (ICD-0): / See list of codes on opposite page

C7. Differentiation/Grade:
- O well differentiated, Grade 1
- O moderately differentiated, Grade II
- O poorly differentiated, Grade III
- O undifferentiated
- O borderline malignancy
- O grade unknown

C8. AJCC Stage (Pathologic)

C8. T-Primary Tumor: O Primary tumor cannot be assessed *(Proceed to C9.)*

O No evidence of primary tumor *(Proceed to C9.)*

O FIGO 1: Tumor limited to ovaries *(Proceed to C8.1.)*

O FIGO 2: Tumor involves one or both ovaries with pelvic extension *(Proceed to C8.2.)*

O FIGO 3: Tumor involves one or both ovaries with microscopically confirmed peritoneal implants outside the pelvis and/or regional lymph node metastasis *(Proceed to C8.3.)*

C8.1. FIGO 1:

O FIGO 1a:	Tumor limited to one ovary; capsule intact, no tumor on ovarian surface, no ascites present containing malignant cells
O FIGO 1b:	Tumor limited to both ovaries; capsules intact, no tumor on ovarian surface, no ascites present containing malignant cells
O FIGO 1c:	Tumor limited to one or both ovaries with any of the following: capsule ruptured, tumor on ovarian surface, malignant cells in ascites or peritoneal washing

C8.2. FIGO 2: O FIGO 2a: Extension and/or implants on uterus and/or tubes

O FIGO 2b: Extension to other pelvic tissues

O FIGO 2c: Pelvic extension (2a or 2b) with malignant cells in ascites or peritoneal washing

C8.3. FIGO 3: O FIGO 3a: Microscopic peritoneal metastasis beyond pelvis

O FIGO 3b: Macroscopic peritoneal metastasis beyond pelvis 2 cm or less in greatest dimension

O FIGO 3c: Peritoneal metastasis beyond pelvis more than 2 cm in greatest dimension and/or regional

C9. N-Regional Lymph Nodes O Regional lymph nodes cannot be assessed

O No regional lymph node metastasis

O Regional lymph node metastasis

C10. M-Distant Metastasis O Presence of distant metastasis cannot be assessed

O No distant metastasis

O Distant metastasis (excludes peritoneal metastasis) (FIGO 4)

OVARIAN CANCER RISK AND SURVIVAL STUDY

D. PRIMARY TREATMENT

D1. Surgery (or biopsy only) Performed: ○ No ○ Yes

If no surgery or biopsy performed:

D1.1. Reason:

○ Never planned

○ Planned, but patient refused

○ Planned, but not performed for other reason (see D1.1.2.)

D1.1.2. Specify reason:

Proceed to "Chemotherapy Regimen" on page 13

D2. Date of Surgery/Biopsy: mo / da / yr (Use 02/02/2020 if unknown)

D3. Type of Laparotomy:

○ Pfannenstiel incision

○ other transverse incision

○ low abdominal midline incision

○ lower and upper abdominal midline incision

○ other laparotomy

○ not applicable

○ unknown, not recorded

D4. Type of Surgery:

Unilateral salpingo-oophorectomy:

○ No ○ Yes ○ Unknown

Bilateral salpingo-oopherectomy:

○ No ○ Yes ○ Unknown

Total abdominal hysterectomy:

○ No ○ Yes ○ Unknown

Supracervical hysterectomy:

○ No ○ Yes ○ Unknown

D4. Type of Surgery (cont'd):

Omentectomy:

○ No ○ Yes ○ Unknown

Pelvic lymph node resection:

○ No ○ Yes ○ Unknown

Small bowel resection:

○ No ○ Yes ○ Unknown

Large bowel resection:

○ No ○ Yes ○ Unknown

Other abdominal visceral resection:

○ No ○ Yes ○ Unknown

Urinary tract resection:

○ No ○ Yes ○ Unknown

Colostomy:

○ No ○ Yes ○ Unknown

Appendectomy:

○ No ○ Yes ○ Unknown

D5. Biopsies Performed:

Cul de sac:

○ Negative for cancer ○ Positive for cancer ○ Not performed ○ Unknown

Diaphragm:

○ Negative for cancer ○ Positive for cancer ○ Not performed ○ Unknown

Omentum:

○ Negative for cancer ○ Positive for cancer ○ Not performed ○ Unknown

Pericolic gutters, NOS:

○ Negative for cancer ○ Positive for cancer ○ Not performed ○ Unknown

Bladder:

○ Negative for cancer ○ Positive for cancer ○ Not performed ○ Unknown

Colon:

○ Negative for cancer ○ Positive for cancer ○ Not performed ○ Unknown

Distal ureters:

○ Negative for cancer ○ Positive for cancer ○ Not performed ○ Unknown

D5. Biopsies Performed (cont'd):

Genital organs:

○ Negative for cancer ○ Positive for cancer ○ Not performed ○ Unknown

Pelvic lymph nodes:

○ Negative for cancer ○ Positive for cancer ○ Not performed ○ Unknown

Para-aortic lymph nodes:

○ Negative for cancer ○ Positive for cancer ○ Not performed ○ Unknown

Rectosigmoid colon:

○ Negative for cancer ○ Positive for cancer ○ Not performed ○ Unknown

Rectum:

○ Negative for cancer ○ Positive for cancer ○ Not performed ○ Unknown

Small intestine:

○ Negative for cancer ○ Positive for cancer ○ Not performed ○ Unknown

Suspicious sites:

○ Negative for cancer ○ Positive for cancer ○ Not performed ○ Unknown

Other:

○ Negative for cancer ○ Positive for cancer ○ Not performed ○ Unknown

If Other, specify site:

D6. All Gross Disease Removed: ○ No ○ Yes ○ Unknown, not recorded

(Includes all primary and metastatic tumor sites)

D7. Macroscopic Residual Disease at Conclusion of Primary Operation:

Abdomen: ○ no residual disease
○ 1 cm or smaller
○ >1 to 2 cm
○ >2 cm
○ residual NOS

Pelvis: ○ no residual disease
○ 1 cm or smaller
○ >1 to 2 cm
○ >2 cm
○ residual NOS

D8. Percentage of Tumor Cytoreduction (debulking) During Primary Operation:

- O none
- O less than 25%
- O 25-49%
- O 50-74%
- O 75-99%
- O 100%
- O unknown, not recorded

D9. Number of Remaining Nodules of Tumor at Conclusion of Primary Operation:

- O none
- O less than 10 nodules
- O 10-20 nodules
- O more than20 nodules, dissemination
- O unknown, not recorded

D10. Type of Primary Surgeon:

- O gynecologic oncologist
- O obstetrician/gynecologist
- O surgical oncologist
- O general surgeon
- O urologist
- O fellow, resident, intern, medical student
- O general practitioner
- O not applicable
- O unknown

D11. Surgical Complications:

	EARLY (1-7 days)	LATE (8-30days)
Anesthesia:	○ No ○ Yes ○ Unknown	○ No ○ Yes ○ Unknown
Hemorrhage, delayed:	○ No ○ Yes ○ Unknown	○ No ○ Yes ○ Unknown
Hemorrhage, immediate:	○ No ○ Yes ○ Unknown	○ No ○ Yes ○ Unknown
Infectious morbidity:	○ No ○ Yes ○ Unknown	○ No ○ Yes ○ Unknown
Intestinal complications:	○ No ○ Yes ○ Unknown	○ No ○ Yes ○ Unknown
Urinary complications:	○ No ○ Yes ○ Unknown	○ No ○ Yes ○ Unknown
Wound dehiscence:	○ No ○ Yes ○ Unknown	○ No ○ Yes ○ Unknown
Death:	○ No ○ Yes ○ Unknown	○ No ○ Yes ○ Unknown
Other complication:	○ No ○ Yes ○ Unknown	○ No ○ Yes ○ Unknown

If Other, specify:

D12. Chemotherapy Given: ○ No *(See D12.1.)*
○ Yes *(See D12.2.)*

If no chemotherapy given:

D12.1. Reason: ○ Never planned
○ Planned, but patient refused
○ Planned, but not performed for other reason (see D12.1.2.)

D12.1.2. Specify reason:

Proceed to "Radiation Therapy" on page 14

If chemotherapy given:

D12.2. Chemotherapy Complications Leading to Toxic Death or Permanent Disability:
○ death
○ disability: see D12.2.1.
○ neither
○ unknown

D12.2.1. Specific chemotherapy complication leading to disability:

Proceed to "Chemotherapy Regimen" on page 13

OVARIAN CANCER RISK AND SURVIVAL STUDY

D 12.3. CHEMOTHERAPY REGIMEN

If chemotherapy given, specify:

Code	Name	Method	Start Date	Stop Date	Complete Cycles
			__/__/____	__/__/____	
			__/__/____	__/__/____	
			__/__/____	__/__/____	
			__/__/____	__/__/____	
			__/__/____	__/__/____	
			__/__/____	__/__/____	
			__/__/____	__/__/____	
			__/__/____	__/__/____	
			__/__/____	__/__/____	
			__/__/____	__/__/____	
			__/__/____	__/__/____	
			__/__/____	__/__/____	
			__/__/____	__/__/____	
			__/__/____	__/__/____	
			__/__/____	__/__/____	

RADIATION THERAPY

D13. Radiation Therapy Given: ○ No ○ Yes

If no radiation therapy given:

D13.1. Reason:

○ Never planned

○ Planned, but patient refused

○ Planned, but not performed for other reason (see D13.1.2.)

D13.1.2. Specify reason:

Proceed to D14. "Other Definitive Therapy Given"

If radiation therapy given, specify:

D13.2. Date Treatment Began: mo / da / yr

(Use 02/02/2020 if unknown)

D13.3. Sites Irradiated:

Pelvis (with or without regional nodes)

○ No ○ Yes ○ Unknown

Whole Abdomen (with or without regional nodes)

○ No ○ Yes ○ Unknown

Other

○ No ○ Yes ○ Unknown

If Other, specify:

D13.4. Date of Last Treatment: mo / da / yr (Use 02/02/2020 if unknown)

D13.5. Total Rad Dose (includes boost dose): (Use 9's if unknown)

D13.6. Radioactive Colloid Administration: ○ No ○ Yes ○ Unknown

D13.7. Radiation Therapy Complications: ○ No ○ Yes ○ Unknown

If yes, specify:

D14. Other Definitive Therapy Given:

○ No *(See D14.1.)*

○ Yes

If yes, specify:

If no other therapy given:

D14.1. Reason:

○ Never planned

○ Planned, but patient refused

○ Planned, but not performed for other reason (see D14.1.2.)

D14.1.2. Specify reason:

DISEASE RESPONSE AND STATUS AFTER COMPLETION OF PRIMARY THERAPY

D15. Diagnostic x-rays or scans:
- O Complete
- O Partial
- O Stable
- O Progression of disease
- O No primary therapy given
- O Unknown, not recorded

D16. Tumor Markers:
- O Complete
- O Partial
- O Stable
- O Progression of disease
- O No primary therapy given
- O Unknown, not recorded

SECOND LOOK OPERATION

D17. Second-Look Operation after Primary Treatment:
- O No
- O Yes
- O Unknown

If no second-look operation performed,

D17.1. Reason:
- O Never planned
- O Planned, but patient refused
- O Planned, but not performed for other reason (see D17.1.2.)

D17.1.2. Specify reason:

Proceed to "Recurrences" on page 18

D18. Results of Second-Look Operation:
- O Negative
- O Microscopically positive
- O Macroscopically positive

D19. Size of Residual Tumor at Second-Look Operation:
- O no residual disease
- O 1 cm or smaller
- O >1 to 2 cm
- O >2 cm
- O residual NOS

D20 Percentage of Tumor Cytoreduction (debulking) during Seond-Look Operation:

- O none
- O less than 25%
- O 25-49%
- O 50-74%
- O 75-99%
- O 100%
- O unknown

D21. Number of Remaining Nodules of Tumor at Conclusion of Second-Look Operation:

- O none
- O less than 10 nodules
- O 10-20 nodules
- O more than 20 nodules, dissemination
- O unknown

E. RECURRENCES

E1. Date of Recurrence: [ ][ ] / [ ][ ] / [ ][ ][ ][ ]
mo da yr

(Use 02/02/2020 if unknown)

E2. Type of Recurrence: ○ local ○ regional ○ distant ○ unknown

E3. Sites of Recurrence:

Pelvis:

○ No ○ Yes ○ Unknown

Ascites:

○ No ○ Yes ○ Unknown

Bone:

○ No ○ Yes ○ Unknown

CNS:

○ No ○ Yes ○ Unknown

Liver:

○ No ○ Yes ○ Unknown

Lung:

○ No ○ Yes ○ Unknown

Lymph Nodes:

○ No ○ Yes ○ Unknown

Pleura:

○ No ○ Yes ○ Unknown

Skin:

○ No ○ Yes ○ Unknown

Other:

○ No ○ Yes ○ Unknown

If Other, specify:

E4. Tumor Markers:

Alphafetoprotein (AFP)
- O Negative
- O Positive
- O Not Done
- O Unknown

If positive, AFP Level

Beta HCG (Human chorionic gonadotropin)
- O Negative
- O Positive
- O Not Done
- O Unknown

If positive, HCG Level

CA-125
- O Negative
- O Positive
- O Not Done
- O Unknown

If positive, CA-125 Level

Carcinoembryonic antigen (CEA)
- O Negative
- O Positive
- O Not Done
- O Unknown

If positive, CEA Level

Hemoglobin
- O Negative
- O Positive
- O Not Done
- O Unknown

If positive, Hemoglobin Level

Other
- O Negative
- O Positive
- O Not Done
- O Unknown

Level if positive:

If Other, please specify:

F. TREATMENT FOR RECURRENCE

F1. Surgery Performed for Recurrence: O No O Yes O Unknown

If no surgery performed,

F1.1. Reason:
- O Never planned
- O Planned, but patient refused
- O Planned, but not performed for other reason (see F1.1.2.)

F1.1.2. Specify reason:

Proceed to F4. "Chemotherapy for Recurrence"

F2. Second-Look Cytoreduction (debulking): O No O Yes O Unknown

If no Cytoreduction performed, or if unknown, proceed to F3. "Palliative Surgery" on page 21
If Cytoreduction was performed, proceed to F2.1.

If Yes:

F2.1. Percentage of Tumor Cytoreduction (debulking):

O none
O less than 25%
O 25-49%
O 50-74%
O 75-99%
O 100%
O unknown

F2.2. All Gross Disease Removed: O No O Yes O Unknown
(Includes all primary and metastatic tumor sites)

F2.3. Macroscopic Residual Disease:

Abdomen:	Pelvis:
O no residual disease	O no residual disease
O 1 cm or smaller	O 1 cm or smaller
O >1 to 2 cm	O >1 to 2 cm
O >2 cm	O >2 cm
O residual NOS	O residual NOS
O unknown	O unknown

F2.4. Number of Remaining Nodules of Tumor:

O none
O less than 10 nodules
O 10-20 nodules
O more than20 nodules, dissemination
O unknown, not recorded

F2.5. Response/Disease Status:

O negative for residual tumor

O positive for residual tumor

O unknown

F3. Palliative Surgery: O No *(Proceed to F3.1.)*

O Yes (planned or given) *(Proceed to F3.2.)*

If no palliative surgery,

F3.1. Reason:

O Never planned

O Planned, but patient refused

O Planned, but not performed for other reason (see F3.1.2.)

F3.1.2. Specify reason:

Proceed to F4., "Chemotherapy for Recurrence" on page 22

If palliative surgery planned or given:

F3.2 Surgery Performed:

O intestinal resection

O intestinal bypass

O inoperable, no surgery

F4. Chemotherapy Given for Recurrence: ○ No *(See F4.1.)*
○ Yes *(See F4.2.)*

If no chemotherapy given,

F4.1. Reason:

○ Never planned

○ Planned, but patient refused

○ Planned, but not performed for other reason (see F4.1.2.)

F4.1.2. Specify reason:

Proceed to "Radiation Therapy for Recurrence" on page 24

If chemotherapy given,

F4.2.. Chemotherapy Complications Leading to Toxic Death or Permanent Disability:

○ death

○ disability: see F4.2.1.

○ neither

○ unknown

F4.2.1. Specific chemotherapy complication leading to disability:

If chemotherapy given for recurrence, see F 4.3. "Chemotherapy Regimen for Recurrence" on page 23

Study ID:_ _ _ _ _ _

OVARIAN CANCER RISK AND SURVIVAL STUDY

F 4.3. CHEMOTHERAPY REGIMEN FOR RECURRENCE

If chemotherapy given, specify:

Code	Name	Method	Start Date	Stop Date	Complete Cycles
			__/__/____	__/__/____	
			__/__/____	__/__/____	
			__/__/____	__/__/____	
			__/__/____	__/__/____	
			__/__/____	__/__/____	
			__/__/____	__/__/____	
			__/__/____	__/__/____	
			__/__/____	__/__/____	
			__/__/____	__/__/____	
			__/__/____	__/__/____	
			__/__/____	__/__/____	
			__/__/____	__/__/____	
			__/__/____	__/__/____	
			__/__/____	__/__/____	
			__/__/____	__/__/____	

OVARIAN CANCER RISK AND SURVIVAL STUDY

RADIATION THERAPY FOR RECURRENCE

F5. Radiation Therapy Given: ○ No *(See F5.1.)*

○ Yes *(See F5.2.)*

If no radiation therapy given,

F5.1. Reason:

○ Never planned

○ Planned, but patient refused

○ Planned, but not performed for other reason (see F5.1.2.)

F5.1.2. Specify reason:

Proceed to "Status at Last Contact" on page 25

If radiation therapy given, specify:

F5.2. Date Treatment Began: mo / da / yr **(Use 02/02/2020 if unknown)**

F5.3. Sites Irradiated:

Pelvis (with or without regional nodes)

○ No ○ Yes ○ Unknown

Whole Abdomen (with or without regional nodes)

○ No ○ Yes ○ Unknown

Other

○ No ○ Yes ○ Unknown

If Other, specify:

F5.4. Date of Last Treatment: mo / da / yr **(Use 02/02/2020 if unknown)**

F5.5. Total Rad Dose (includes boost dose): [ ][ ][ ][ ][ ] (Use 9's if unknown)

F5.6. Radioactive Colloid Administration: O No O Yes O Unknown

F5.7. Radiation Therapy Complications: O No O Yes O Unknown

If yes, specify:

[ ]

G. STATUS AT LAST CONTACT

G1. Date of Last Contact: [ ][ ] / [ ][ ] / [ ][ ][ ][ ] (Use 02/02/2020 if unknown)
mo da yr

G2. Patient Status:

O alive

O deceased

If deceased, specify:

G2.1. Date of Death:

[ ][ ] / [ ][ ] / [ ][ ][ ][ ] (Use 02/02/2020 if unknown)
mo da yr

G2.2 Autopsy Findings:

O no evidence of ovarian cancer

O ovarian cancer present

O not done

O findings unknown

G3. Cancer Status:

O no evidence of ovarian cancer

O ovarian cancer present at last contact

O ovarian cancer status unknown

OVARIAN CANCER RISK AND SURVIVAL STUDY

POST-CHEMOTHERAPY CA-125 VALUES

Date of Blood Draw: (mo / da / yr)	CA-125	CA-125 Level
/ /	○ Negative ○ Positive	
/ /	○ Negative ○ Positive	
/ /	○ Negative ○ Positive	
/ /	○ Negative ○ Positive	
/ /	○ Negative ○ Positive	
/ /	○ Negative ○ Positive	
/ /	○ Negative ○ Positive	
/ /	○ Negative ○ Positive	

Use 02/02/2020 if unknown